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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,504	04/05/2001	Thomas J. Bradbury	900122.420	6823

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EXAMINER

FISHER, MICHAEL J

ART UNIT	PAPER NUMBER
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3629

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,504

Applicant(s)

BRADBURY ET AL.

Examiner

Michael J. Fisher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,6,7,8 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,722,026. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn toward producing a prosthetic using patient-specific, radiological images transmitted over a network to a

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production device. As to claims 8 and 12, the patent does not specifically mention the Internet. It does, however, mention a computer network, which group includes the Internet.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 16 contain the limitation, "selecting a best fit... already manufactured implants." while claims 8 and 14, from which they depend, have the limitation, "...manufacturing the ...device..." Thus, it is unclear and indefinite as to whether the device is manufactured or chosen using the images.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by US PAT 5,683,243 to Andreiko et al. (Andreiko).

As to claim 1, Andreiko discloses a method in a computer system for customized design of an implant (fig 1), that produces a patient-specific, radiological image of a body part (33), converting into a format transmittable over a network (36,30a, best seen in fig 1), creating a computer-based multi-dimensional model (30b, 37 as best seen in fig 1), modifying the model to add or subtract a structure (fig 2b, fig 2f)), producing a set of three-dimensional printing instructions (implicit in that there is a three-dimensional model made) and manufacturing a biomedical implant according to the instructions (abstract).

As to claim 2, Andreiko discloses forming an internal architecture (implicit in that there is necessarily internal architecture as the device is three-dimensional).

As to claim 6, Andreiko discloses capturing data in a computerized form (33,26 in fig 1), converting the data to a multi-dimensional model (30b, 37), modifying the model to include internal architecture (inherent in that every three-dimensional object has internal architecture), converting the model into machine instructions to produce the device (42,30c and 38 in fig 1), manufacturing the device (25), and shipping the device for implantation (inherent in that the device is made and the dentist installs it).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3,7,8 and 12-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Andreiko.

Andreiko discloses a method as discussed above.

As to claim 8 and 14, Andreiko does not teach using the Internet. Andreiko does teach using a computer network (fig 1). It would have been obvious to one of ordinary skill in the art to modify Andreiko by connecting the system to the Internet to ease use of the system and to reduce the cost of a proprietary network.

As to claim 12, Andreiko discloses providing machine instructions to a three dimensional printer (fig 1D).

As to claims 13 and 16, it would have been obvious to one of ordinary skill in the art to use pre-made articles as these would not be only suitable for one person and would therefore, be less expensive.

As to claims 3,7 and 15, Andreiko does not, however, teach transmitting the model to a client or recipient for approval or modification. It would have been obvious to

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one of ordinary skill in the art to first send the model to be approved to reduce the chance for error and improve customer satisfaction.

Claims 4,5,10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreiko as applied to claims 1-3,6-8 and 12-16 above, and further in view of US PAT 6,624,138 to Sung et al. (Sung).

Andreiko discloses a method as discussed. Andreiko does not, however, teach making the device as a drug delivery device.

As to claims 4,5,10 and 11, Sung teaches a method for treating the tissue of a patient with an implantable drug device (abstract, lines 1-5). It would have been obvious to one of ordinary skill in the art to modify the method as disclosed by Andreiko with the drug-implantable device as taught by Sung as Sung teaches this as a good way to introduce drugs for treating patients.

Conclusion

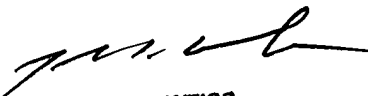
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US PAT 4,575,805 to Moermann et al. teach a method of producing a custom-shaped implant using scanning, US PAT 4,663,720 to Duret et al. teach using computer graphing techniques and images of the patient to produce prosthetics, US PAT 5,150,304 to Berchem et al. teaches using radioscopy to produce an implantable prosthesis, US PAT 6,015,289 to Andreiko et al. teaches using scanning to produce implants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Fisher whose telephone number is 571-272-6804. The examiner can normally be reached on Mon.-Fri. 7:30am-5:00pm alt Fri. off.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MF 
8/20/05


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